CATEGORY IV MONOGRAPH

Throat Lozenges

I) Description:

This monograph applies to products in lozenge form intended to be dissolved in the mouth to help relieve sore throats. The medicinal ingredients, their concentrations and combinations in Category IV products are restricted to those specified in this monograph. The medicinal ingredients must be identified on product labelling by the names given in this monograph.

II) Pharmaceutical Quality:

a) All ingredient (medicinal and nonmedicinal) and finished product specifications should as a minimum meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

b) **Special Notes:**

Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient(s) including its components. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. It is recommended that antimicrobial preservative effectiveness be determined in order to establish that the product is capable of resisting microbial contamination.

III) Ingredients:

a) **Single Medicinal ingredients:**

Analgesic/Anaesthetic Ingredients:

i)	menthol	2 - 20 mg[1]
ii)	phenol	10 - 50 mg
iii)	hexylresorcinol	2 - 4 mg
iv)	benzocaine	2 - 15 mg
v)	dyclonine hydrochloride	1 - 3 mg

vi)	benzyl alcohol	100 - 500 mg
vii)	salicyl alcohol	50 - 100 mg

Demulcent Ingredients:

vii)	slippery elm bark powder	10 - 15 % (200 - 300 mg)
ix)	gelatin - sufficient quantity to form a solid state	
x)	pectin - sufficient quantity to from a solid state	

Antiseptic Ingredients:

xi)	cetylpyridinium chloride	1 - 2 mg
xii)	domiphen bromide	1.5 mg
xiii)	dequalinium chloride	0.25 mg

b) **Combinations of Medicinal Ingredients:**

The concentration of the individual ingredients must not exceed the maximum value permitted as single medicinal ingredients.

i) menthol + eucalyptus oil 0.2 - 15 mg[1]
ii) menthol + hexylresorcinol
iii) benzocaine + cetylpyridinium chloride
iv) benzocaine + phenol
v) benzocaine + menthol
vi) any demulcent + any anaesthetic/analgesic
vii) any demulcent + any antiseptic

[1] There would be no objection to declaration of menthol and eucalyptus oil as a percentage provided that the minimum dose in terms of mg is met and that this information is provided with the application.

c) **Nonmedicinal Ingredients:**

Nonmedicinal ingredients must be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives.

Herbal ingredients are not permitted.

IV) **Labelling:**

a) This monograph describes those requirements that are specific to this class of drugs. Other requirements described in the *Regulations to the Food and Drugs Act* and in the *Guide for the Labelling of Drugs for Human Use* must also be met.

b) **Directions for Use:**

i) **Indications**

The primary indication should be to the effect:

For the temporary relief of sore throat

In addition the following indications/claims may also be used as appropriate:

1) **analgesic/anaesthetic** ingredients

for the temporary relief of pain of sore throat

2) **demulcent** ingredients

for the protection of irritated area in throat

3) **menthol 1 - 20 mg**

helps ease/relieve nasal congestion, makes nasal passages feel clearer

4) **menthol 5 - 20 mg** or,
menthol 5 - 20 mg and eucalyptus oil 0.2 - 15 mg

for the temporary relief of coughs

5) **hexylresorcinol, cetylpyridinium chloride, domiphen bromide, phenol or dequalinium**

antiseptic

ii) **Unacceptable Indications/Claims**

Any reference to treatment of sore mouth, irritated mouth, mouth ulcers or cold sores.

iii) **Dosage**

1) **menthol/eucalyptus oil:**

adults and children 2 years and over, dissolve one lozenge slowly in the mouth as required.

2) **phenol:**

adults and children 6 years and over, one lozenge to be dissolved in the mouth, may be repeated every 2 hours as needed to a maximum daily dose of 300 mg (as expressed in number of dosage units (lozenges))

3) **hexylresorcinol, benzocaine, benzyl alcohol, dyclonine hydrochloride, cetylpyridinium chloride, domiphen bromide, dequalinium or salicyl alcohol:**

adults and children 2 years and over, one lozenge to be dissolved slowly in the mouth, may be repeated every 2 hours as needed

4) **slippery elm bark powder:**

adults and children 2 years and over, one lozenge to be dissolved slowly in the mouth every 1 - 2 hours up to a maximum of 6 g per day (as expressed in number of dosage units (lozenges))

5) **gelatin or pectin:**

adults and children 2 years and over, one lozenge to be dissolved slowly in mouth, may be repeated as needed

iv) **Warnings**

1) for **relief of sore throat** claims:

if symptoms are severe or persist for more than 2 days consult a doctor

2) for **antitussive** claim:

if cough worsens, persists for more than 7 days or is accompanied by high fever consult a doctor

V) **References:**

1) **Federal Register** vol 47, No 101 May 25, 1982. pp. 22779-22905, Over the Counter Oral Healthcare and Discomfort Drugs, Establishment of a Monograph.

2) **Federal Register** vol 53, No 17, January 27, 1988. pp. 2457-2461, Oral Healthcare Products for Over the Counter Human Use, Proposed Rules.

3) **Third Report of the Expert Advisory Committee, Nonprescription Cough Cold Remedies**, Ministry of National Health and Welfare, 1989. pp. 4-9.

4) **American Handbook of Nonprescription Drugs**, Ninth Edition, 1990, American Pharmaceutical Association.

5) **Federal Register** vol 52, No 155, August 12, 1987. pp. 30045-30057, Final Monograph for Over the Counter Antitussive Drug Products.

6) **Federal Register** vol 55, No 192, October 3, 1990. pp. 40381-40383, as above.

7) **Federal Register** vol 41, No 176, September 9, 1976. pp. 38405-38424, Cough and Cold, Allergy, Bronchodilator and Antihistamine Products for Over the Counter Use.

8) **Martindale, The Extra Pharmacopoeia,** 29th Edition, 1989. The Pharmaceutical Press, London.

9) **Remington's Pharmaceutical Sciences,** 18th Edition, 1990. Philadelphia College of Pharmaceutical Sciences.

10) **Principles and Practice of Disinfection, Preservation and Sterilisation**, edited by AD Russell, WB Hugo and GAJ Ayliffe, 1982. Blackwell Scientific Publications.

Appendix I

Formulated Preparations

Proper Name	**USP** 1995	**BP** 1993	**BPC** 1976
benzocaine	X	X	X
benzyl alcohol	X	X	X
cetylpyridinium chloride	X	X	X
cetylpyridinium chloride lozenges	X		
dequalinium chloride		X	X
domiphen bromide		X	X
dyclonine hydrochloride	X		X
gelatin		X	X
hexylresorcinol	X	X	X
hexylresorcinol lozenges	X		
menthol	X		X
pectin	X		
phenol	X	X	X